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Chairman Price, Ranking Member Rogers and distinguished Members of the Subcommittee, I appreciate the opportunity to appear today to discuss the nation's biosurveillance efforts. I am honored to testify with my colleague, Under Secretary for the DHS Science and Technology (S&T) Directorate, Dr. Tara O'Toole, and I appreciate the opportunity to hear from Dr. Bernard Goldstein, the esteemed lead author of the recent Institute of Medicine (IOM) report on Biosurveillance.

The Office of Health Affairs (OHA) leads the Department of Homeland Security's biodefense activities. OHA works closely with S&T to ensure the nation has robust technologies to detect biological agents that pose harm to the nation. Deterrence, detection, preparation for, and response to biological threats, whether man-made or naturally occurring, requires coordination both within DHS and between federal, state and local partners. In addition, OHA works in close collaboration with our partners at the Department of Health and Human Services (HHS) – specifically the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Centers for Disease Control and Prevention (CDC) – on the BioWatch program, maintaining a biosurveillance picture, and biological incident medical response efforts.

Office of Health Affairs Current Biosurveillance Capabilities

Biosurveillance is but one piece of a larger biodefense strategy. Since my confirmation as the Assistant Secretary for OHA in August 2009, I have refocused OHA programs to the mission of ensuring we have an end-to-end approach and ensuring that biological surveillance and detection are part of the continuum of response to an incident. Reliable early detection of biological incidents that can sicken or kill people can save lives by allowing the opportunity to provide prompt medical countermeasures to the people exposed.

The Office of Health Affairs currently manages two biosurveillance capabilities: the BioWatch program and the National Biosurveillance Integration Center (NBIC).

National Biosurveillance Integration Center

Under the Implementing Recommendations of the 9/11 Commission Act (9/11 Act), Congress mandated DHS establish the National Biosurveillance Integration Center (NBIC) to enhance the capacity of the federal government to rapidly identify, characterize, localize, and track biological events of national concern through integration and analysis of data relating to human health, as well as animal, plant, food, and environmental monitoring systems (both national and international).

NBIC was authorized in FY 2007. To date, seven federal departments have entered into Memoranda of Understanding (MOU) with NBIC to begin the process of analyzing data, sharing information, and providing subject matter expertise on biological incidents. The seven MOUs are between NBIC and the Departments of State, Health and Human Services, Commerce, Veterans Affairs, Agriculture, Defense, and Interior.

Since it was initiated, NBIC has provided critical biosurveillance information on a number of incidents including the 2009 Salmonella St. Paul event and the 2009-H1N1 pandemic. NBIC aims to identify biological incidents early and alert senior leaders of emerging threats against the population. It is critical that the nation has the ability to recognize and track biological events early to prevent or mitigate associated consequences.

NBIC received $8 million in FY 2010 and is requesting $7 million in FY 2011 to fund the center and its operations. This level of funding is sufficient to maintain NBIC's current capability. To enhance the ability of NBIC to gather and analyze biosurveillance information, I have directed my staff to reexamine current procedures and operations. We plan to aggressively work to improve coordination with our state and local partners that can provide sentinel information for the country, such as North Carolina, Minnesota, and Washington. FY10 funding for NBIC included an additional $5 million to support a demonstration project with the North Carolina Collaboratory for Bio-Preparedness, which includes the University of North Carolina, North Carolina State University, and the SAS Institute renowned for their advanced computing and information analytical capability. We hope that this pilot biosurveillance project may validate the efficacy of improved information sharing between public and private information sources. North Carolina has advanced public health surveillance information and wants to further this capability by including private partners' information and merging other biosurveillance disciplines, such as veterinary data. Minnesota is nationally known for their superior Food Defense capabilities through information analysis and Washington State has demonstrated advanced capability to integrate critical infrastructure analysis in their decision making schemes.

We realize that there is tremendous biosurveillance work being performed outside of the federal government and we have plans in place to increase engagement with states, the private sector, and international partners while remaining vigilant to protect data security and privacy.

The BioWatch Program:

The BioWatch program, first announced during the 2003 State of the Union, is the nation's first early warning network of sensors to detect biological attacks. OHA is responsible for managing the day-to-day operations of the BioWatch system and S&T supports OHA's acquisition and procurement of new BioWatch technologies, referred to as "Generation 3" or "Gen 3" technology. The BioWatch program also partners with

CDC through verification of assays used in the analysis for biological agents and with the technical analysis and subject matter expertise of potential biological detections.

The mission of the BioWatch program is to provide the nation the greatest lead time possible to respond to the intentional release of a biological agent. Because of the rapidity of the decision cycle and the need for a rapid deployment of medical countermeasures, the ability to quickly identify a biological agent will potentially save lives.

The BioWatch Program is planning and executing exercises in BioWatch jurisdictions to assist state and local responders in testing public health response capabilities and to review and strengthen notification protocols. We are also encouraging regionalization of our programs where appropriate. I recently attended a multi-jurisdictional BioWatch exercise on the west coast, which was the first time that two completely separate sites participated in an exercise of the system. We use these exercises to better refine the systems and align best practices. This regional approach is imperative for building a resilient nation capable of identifying and responding to an intentional release of a biological agent.

Generation 3 Technology

In addition to improving the interaction with public health and emergency management at the state and local level, we are moving detection science forward with our Generation 3 program. Since 2003, BioWatch capabilities have undergone several technological development phases. The current technology deployed to BioWatch jurisdictions are commonly referred to as Generation 1 and 2. The same technology and approaches are used in the Generations 1 and 2 systems with the difference being when each system was deployed.

Generation 3 represents the first advancement in BioWatch technologies beyond manual filter collection and laboratory analysis by building a "lab in the box" detection system. After a rigorous and transparent Request for Proposals (RFP) process, I am pleased to share that we recently awarded contracts to two vendors to bring their systems in for independent testing. Testing plans are being coordinated with the federal biosurveillance community and will be approved independently by the S&T Test and Evaluation branch. Additionally, an independent test evaluator is being utilized to ensure full and comprehensive testing before any deployment takes place.

A fully autonomous system that can perform its duties reliably and accurately in a variety of locations and environmental conditions including weather and pollutant extremes would represent a tremendous leap forward in surveillance technology. We do not take this challenge lightly and together with our partners at S&T, have developed a rigorous testing and evaluation program that is the model for future new technology acquisition at DHS. If these new detectors cannot meet our demands we will not deploy defective technology.

We are very hopeful that the technological challenges can be overcome and we will continue to develop further generations of BioWatch, including the ability to identify agents that have been genetically manipulated. It is absolutely imperative that we develop this technology as a part of a coordinated detection and surveillance system. The key to biosurveillance is to have multiple overlapping and redundant systems with no single point of failure. We are seeking cheaper, faster, and more agile systems – our state and local officials and operators are seeking such capabilities and we support this approach.

Congress appropriated $89.5 million in fiscal year 2010 for BioWatch and the Administration is requesting $173.5 million in fiscal year 2011. Approximately $89.5 million in 2011 will be used to maintain the current network, establish a more comprehensive quality assurance program, optimize the BioWatch network to maximize probability of detection of an attack, expand the current BioWatch exercise program that includes extensive interaction with federal, state and local partners, provide state and local partners better situational awareness with web-based modeling capabilities backed up by a robust reach-back capability to the national laboratories, and work with the interagency on technology evaluations.

Approximately $84 million will be used to procure and potentially deploy units for a four city operational field test of the Generation 3 system. If one or both candidates pass current testing, we plan to procure units for deployment into other existing BioWatch jurisdictions. The four-city operational testing phase will test BioWatch capabilities in a variety of outdoor and indoor environments to ensure the systems operate properly before committing the government to a large-scale buy. All of the cities have not yet been selected. I will keep you informed when those selections are made.

In addition, we have conducted several modeling projections and have concluded that we should expand BioWatch to approximately 50 locations throughout the nation to provide an appropriate level of protection against the assessed risk. This would ensure that a third of the population would be monitored and protected against biological threats. Based on the current risk and modeling, there is little advantage to increasing capacity above the 50 cities identified. The current and FY11 proposed budget for BioWatch relates strictly to deploying the new Generation 3 systems in existing BioWatch jurisdictions. As we continue to evaluate expanding BioWatch, we will maintain open communication and dialogue with all of you.

Recent Reports and Examinations of Biosurveillance Capabilities

Throughout 2009 and 2010, several important reports have been released by various organizations examining the nation's biosurveillance capabilities. These reports include:

- The National Academy of Sciences Report: BioWatch and Public Health Surveillance: Evaluation Systems for the Early Detection of Biological Threats;

- The Government Accountability Office Report: Biosurveillance: Developing a Collaboration Strategy is Essential to Fostering Interagency Data and Resource Sharing; and
- The Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism interim progress Report: The Clock is Ticking.

My office has reviewed each of the reports closely and used their advice to improve our own efforts. I have reviewed all of the programs within my office to ensure we are continuing to strengthen and prepare against biological threats to provide the nation with the strongest capabilities available.

The National Academy of Sciences' Report: BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats

Language included in the House Report to the *Department of Homeland Security Appropriations Bill* for Fiscal Year 2009 directed the National Academy of Sciences (NAS) to "evaluate the program [BioWatch] and compare it to an enhanced surveillance system that relies on U.S. hospitals and the U.S. public health system." In December 2009, NAS released its report and included 11 recommendations to improve BioWatch and surveillance capabilities. Two recommendations focused on the need for BioWatch to better support state and local jurisdictions via additional funding (to support laboratory functions) and additional activities to support response to BioWatch Actionable Results (BARs). Four recommendations focused on BioWatch technology development including: further collaboration with S&T and other federal partners (HHS, EPA, DoD, etc.); and, a coordinated and thorough testing regime for the development of Generation 3 technology. Three recommendations supported enhanced HHS/DHS coordination and collaboration to better inform decision makers of biological incidents/issues affecting public health including: the establishment of a mechanism to receive advice/input on technical and operational issues of BioWatch; and, establishing a workforce with sufficient public health strengths and competencies. Two recommendations were HHS-specific and included recommendations regarding their surveillance systems. OHA has worked to begin addressing the recommendations included in the NAS report.

Over the last 18 months, OHA has invested significant time and effort into strengthening and restoring critical relationships with state and local jurisdictions, improving the level of information sharing between federal, state, and local partners, and exercising the bionotification protocols from the point of receiving a positive detection of DNA material through identification of an actual attack.

We heard the concerns from the public health laboratory community about the need to improve our relationship, and we have acted. First, we have reduced the operational burden on laboratories by cross-training BioWatch laboratory technicians in public health duties, and the public health laboratories are learning how to conduct BioWatch analysis. This arrangement allows greater laboratory surge capability and provides great dividends to meet both communities' needs. This new arrangement paid off significantly during the 2009-H1N1 pandemic when lab technicians were called to test samples. Staff members

were able to balance responsibilities and provided available service to the nation. Second, we have developed a cost model to capture the indirect BioWatch costs (overhead) on the laboratory and are currently discussing this with the public health community before proposing this in our budgets.

Regarding the NAS recommendations focused on the development of BioWatch technology, we agree with the importance of maintaining transparency and technical veracity of the BioWatch program. As I detailed earlier in my testimony, I am committed to proper testing and transparency as a new technology is developed. OHA has brought in an outstanding team of capable technical experts together to execute the BioWatch program. We have a strong relationship with S&T in both coordinating developmental programs and providing technical expertise during current operations. While recognizing some information sharing challenges because of security concerns, we have been able to share more technical information with public health officials on the capabilities and limitations of the current BioWatch system as well as with other state and local officials involved with the program.

Regarding NAS' recommendations supporting enhanced coordination and collaboration to better inform decision makers of biological incidents/issues affecting public health, I am committed to making sure we don't work in a vacuum and plan to make sure that state and local officials have the full availability and support of U.S. government subject matter experts. I've directed my staff to assemble an advisory committee and to hold a kickoff by next summer. We are engaging with other expert groups, managed via S&T, on our operational assay testing program and the Generation 3 test plan design. We have observed the value of seasoned professionals' advice provided by the Homeland Security Advisory Council (HSAC) and others in the Department, and we look forward to establishing a similar arrangement for the BioWatch program.

Lastly, while the final two recommendations were focused on HHS efforts in biosurveillance, we likewise support improved methods of disease surveillance. As NAS found in their report, and we endorse, we see disease surveillance, syndromic surveillance, and early detection as complementary efforts supporting the nation's quick recognition of a potentially catastrophic biological attack, not competing efforts. NBIC will continue pursuing other-than-medical sources worldwide and share this information with HHS.

Government Accountability Office (GAO) Report: Biosurveillance: Developing a Collaboration Strategy is Essential to Fostering Interagency Data and Resource Sharing

In December 2009, the GAO released its Report, "Biosurveillance: Developing a Collaboration Strategy is Essential to Fostering Interagency Data and Resource Sharing." This report examined NBIC's ability to analyze data and provide biosurveillance information on ongoing biological incidents. The report was supportive of the unique mission of NBIC and the value such a center provides to the nation. It included two recommendations. First, GAO recommended that NBIC work to finalize a strategy for more effectively collaborating with current and potential National Biosurveillance

Integration System (NBIS) members, by (1) clearly defining NBIC's mission and purpose, along with the value of NBIS membership for each agency; (2) addressing challenges to sharing data and personnel, including clearly and properly defining roles and responsibilities in accordance with the unique skills and assets of each agency; (3) developing and achieving buy-in for joint strategies, procedures, and policies for working across agency boundaries. Secondly, GAO recommended NBIC establish and use performance measures to monitor and evaluate the effectiveness of collaboration with current and potential NBIS partners.

I agree with the general findings of the GAO report in that it has been difficult to share information between federal partners. I have directed my staff to engage with our federal partners to review the NBIC mission and implementation plan. In addition, as I detailed earlier in my testimony, we are taking a new approach to collaborating with state and private sector partners. I assure you that as we move forward in improving NBIC, the center will continue to provide senior leaders with critical biosurveillance data during incidents. I look forward to hearing your thoughts on how to better direct and further develop NBIC.

Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission) Interim Progress Report: "The Clock is Ticking"

On October 21, 2009, the WMD Commission released its report, "The Clock is Ticking." Specific concerns raised in the report include: the lack of development of a common understanding of the threat of biological terrorism; the lack of a senior official leading the biodefense effort; the lack of resources supporting the Biomedical Advanced Research and Development Authority (BARDA) and Project BioShield; and, the lack of improvement in general disease surveillance efforts.

We appreciate the WMD Commission calling attention to biological terrorism. We agree that bio-threats, along with a nuclear event, are the two highest risk catastrophic events that our nation faces. However, we respectfully disagree with some of the report's findings and their recent scorecard update.

As a prior state public health official, I know the value of preparedness and exercising for significant biological events. I've directed my team to continue to focus the BioWatch exercises on working with the state and local BioWatch Advisory Committees on post-recognition actions. We're encouraged by the S&T interagency efforts to address the large biological characterization, decontamination and recovery problem through their pilot in Seattle, and networking the laboratory community through the Integrated Consortium of Laboratory Networks (ICLN). Challenges remain in areas such as medical countermeasures distribution and the development of additional medical countermeasures, but I assure you that Dr. O'Toole and I, as well as the DHS leadership, are committed to improving efforts.

Conclusion

Chairman Price, Ranking Member Rogers and Members of the Subcommittee, thank you for taking the time today to discuss the nation's biosurveillance efforts. I will be glad to answer any questions you may have.